Use of a Cast Compared with a Functional Ankle Brace After Operative Treatment of an Ankle Fracture

A Prospective, Randomized Study

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Background: Controversy continues with regard to the optimal postoperative care after open reduction and internal fixation of an ankle fracture. The hypothesis of this study was that postoperative treatment of an ankle fracture with a brace that allows active and passive range-of-motion exercises would improve the functional recovery of patients compared with that after conventional treatment with a cast. Thus, the purpose of this prospective, randomized study was to compare the long-term subjective, objective, and functional outcome after conventional treatment with a cast and that after use of functional bracing in the first six weeks following internal fixation of an ankle fracture.

Methods: One hundred patients with an unstable and/or displaced Weber type-A or B ankle fracture were treated operatively and then were randomly allocated to two groups: immobilization in a below-the-knee cast (fifty patients) or early mobilization in a functional ankle brace (fifty patients) for the first six postoperative weeks. The follow-up examinations, which consisted of subjective and objective (clinical, radiographic, and functional) evaluations, were performed at two, six, twelve, and fifty-two weeks and at two years postoperatively.

Results: There were no perioperative complications in either study group, but eight patients who were managed with a cast and thirty-three patients who were managed with a brace had postoperative complications, which were mainly related to wound-healing. Two patients in the group treated with a cast had deep-vein thrombosis. All fractures healed well in both groups. The difference between the two groups with respect to the complication rate was significant ($p = 0.0005$). No significant differences between the study groups were observed in the final subjective or objective (clinical) evaluation. At the two-year follow-up examination, the average score (and standard deviation) according to the ankle-rating scale of Kaikkonen et al. was 85 ± 9 points for the group treated with a cast and 83 ± 10 points for the group treated with a brace, and the average ankle score according to the system of Olerud and Molander was 87 ± 8 points and 87 ± 9 points, respectively.

Conclusions: The long-term functional outcome after postoperative treatment of an ankle fracture with a cast and that after use of a functional brace are similar. Although early mobilization with use of a functional ankle brace may have some theoretical beneficial effects, the risk of postoperative wound complications associated with this treatment approach is considerably increased compared with that after conventional cast treatment. Thus, the postoperative protocol of treatment with a functional brace requires refinement before it can be generally advocated for use after operative treatment of an ankle fracture.

Level of Evidence: Therapeutic study, Level I-1b (randomized controlled trial [no significant difference but narrow confidence intervals]). See Instructions to Authors for a complete description of levels of evidence.

Ankle fracture is the most common type of fracture treated in hospitals, with an overall estimated incidence of 100 fractures per 10^5 person-years[1,2], and the rate has been constantly increasing in both young active patients and in the elderly over the last several decades[1,3-6]. Operative treatment of a fracture is indicated when congruity of the ankle joint has been compromised[7,8]. The normal anatomy and biomechanics of the ankle joint can generally be restored with open reduction and internal fixation but only at the expense of increased costs and risks related to operative treatment[9-11]. Currently, the indi-

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cations for operative treatment of an ankle fracture are relatively clear, but controversy remains with regard to many aspects of the postoperative care of these fractures[4,9-16]. In addition to conventional postoperative immobilization in a cast, functional treatment (early movement of the ankle and even immediate weight-bearing) has been widely accepted for use after internal fixation of an ankle fracture[11,13,14,16-28], but only a few of these studies have been randomized and prospective.

A semirigid functional orthosis has been shown to reduce postural sway, improve proprioceptive function of the injured ankle, and provide better functional results, at least in the short-term, for stable lateral malleolar fractures and injuries to the lateral ligaments of the ankle[4,10,14,25,27,29-32]. Consequently, it has been speculated that early controlled mobilization could also be beneficial in the postoperative care of unstable ankle fractures after open reduction and internal fixation[10,19,28]. The hypothesis of this study was that postoperative treatment of an ankle fracture with a brace that allows active and passive range-of-motion exercises would improve the functional recovery of patients compared with that after conventional cast treatment. A prospective, randomized two-year follow-up study of postoperative management of patients with a displaced fracture of the ankle was carried out, with use of subjective, clinical, radiographic, and functional evaluations, to compare the results after immobilization in a cast with those after use of a functional ankle brace.

Materials and Methods

Patients

One hundred consecutive patients who had an acute ankle fracture (one seen less than seventy-two hours after the injury) that was displaced or unstable, classified as type A or B according to the AO-Weber system[8,33], and treated operatively at our hospital between November 1995 and April 1998 were included in the study. Our exclusion criteria included a fracture that was considered insufficiently stable for early mobilization after the operation, an open fracture, a pilon fracture of the tibia, a Weber type-C fracture of the ankle requiring screw placement across the syndesmosis, a patient with other severe injuries, and a patient who was unable to cope with either of the two postoperative protocols.

All subjects were informed of the study procedure, the purpose of the study, and any known risks, and all gave informed consent. The study was conducted in conformity with the principles of the Helsinki II Declaration and was approved by the Committee of Ethics on Human Research at our clinic and the supporting institution.

All patients who were enrolled in the study were treated surgically with open reduction and internal fixation according to AO/ASIF methods[9]. The precise indications for surgery were unimalleolar, bimalleolar, or trimalleolar injury and/or fibular displacement of >2 mm in any plane on the radiographs. No attempt was made to repair possible ligamentous or other soft-tissue injuries. Spinal anesthesia was used for all patients. Postoperatively, the patients were randomly allocated, with use of sealed envelopes, to treatment with either a cast or a functional ankle brace for the first six weeks after the operation. Until the actual randomization, the ankles in both groups were placed in a FoamWalker leg brace (Aircast, Summit, New Jersey). The patients managed with conventional treatment wore a below-the-knee plaster cast and used crutches for the first two weeks, at which point the stitches were removed and partial weight-bearing was allowed in a fiberglass short leg walking cast for the next four weeks. Full weight-bearing was allowed at four weeks, and the cast was removed at six weeks after the operation. The other group was managed with a functional Air-Stirrup ankle brace (Aircast) that was applied immediately after the operation. The weight-bearing protocol was identical to that used in the group treated with a cast. Daily active and passive range-of-motion exercises of the ankle and subtalar joints without the brace were encouraged immediately postoperatively and until normal gait was achieved.

Six weeks after the injury, the cast or brace was removed and more active exercises were recommended. These included rising on the toes with the feet internally rotated, with the feet pointing straight ahead, and with the feet externally rotated; isometric contractions of the dorsiflexor muscles of the ankle with the foot positioned underneath and pressing up against a heavy piece of furniture; and training on a one-way balance board (both in the forward-backward and sideways directions). The patients were advised to perform each exercise in a series of ten repetitions, five to ten times a day. Running, stair-climbing, and participation in sports were allowed only after a full range of motion of the ankle had been achieved. Patients with mechanical or functional instability of the ankle were also instructed to use adhesive strapping or any other type of supportive ankle orthosis during athletic or any other strenuous activities for three to six months after the ankle injury.

Follow-up Evaluation

The recovery of the patients was assessed clinically with use of subjective, objective, and radiographic evaluation criteria at two, six, twelve, and fifty-two weeks and at two years postoperatively. To limit the bias inherent in all clinical examinations and manual tests, the follow-up examinations and rating scores at twelve and fifty-two weeks and at two years were performed by the same independent physician who had not been involved in the actual treatment of any of the patients. Standardized anteroposterior and lateral radiographs were made postoperatively at two weeks, six weeks, and later, if indicated, to assess fracture-healing and alignment. Swelling of the ankle (as determined by the difference between the injured and the uninjured ankle with respect to the circumference of the ankle at the level of the malleoli) and atrophy of the calf muscles (as determined by the difference in the circumferences of the calf muscle 10 cm distal to the tibial tuberosity) were measured with a tape measure. The range of motion from maximum active dorsiflexion to maximum active plantar flexion of both the injured and the uninjured ankle was determined with use of a goniometer. In addition to these criteria, the functional recovery of the patients was evaluated with use of two different protocols: the scoring

TABLE I Baseline Characteristics of the Patients

	Group Treated with a Cast (N = 50)	Group Treated with a Brace (N = 50)
Male/female	31/19	25/25
Age* *(yr)*	41 ± 13	41 ± 13
Weight* *(kg)*	82 ± 15	77 ± 15
Height* *(cm)*	174 ± 9	173 ± 9
Body-mass index* *(kg/m^2)*	27 ± 4	26 ± 4
Left/right side	20/30	22/28
Dominant/nondominant ankle	30/20	31 /19
Weber type-A/type-B fracture	2/48	2/48
Unimalleolar/bimalleolar/trimalleolar fracture	29/14/7	30/14/6
Transverse/oblique/spiral fracture	16/33/1	13/36/1
Deltoid ligament injury	1	5
Skin abrasion	4	2
Time from injury to surgery* *(hr)*	30 ± 19	25 ± 17
Duration in hospital* *(days)*	3 ± 1	3 ± 1

*The values are given as the mean and the standard deviation.

system of Olerud and Molander[34] was used at the six, twelve, and fifty-two-week and two-year follow-up visits, and the scoring scale of Kaikkonen et al.[35], which was specifically developed and validated for the evaluation of the functional recovery of an injured ankle, was used at the twelve and fifty-two-week and two-year follow-up examinations. Both of these scoring systems rate nine parameters relating to the symptoms and the function of the ankle after the injury, with use of a 100-point scale. Furthermore, the time between the operation and return to work was documented for all patients.

Statistical Analysis

The data were analyzed with use of a personal computer and SPSS statistical software (version 7; SPSS, Chicago, Illinois). Comparison of the differences between the groups was made with the Student t test for continuous variables and with the chi-square test for categorical variables. In all tests, an alpha level of <0.05 was considered significant. The given significance levels refer to two-tailed tests. The results are given as the mean and the standard deviation.

Results

Data on the Patients

The baseline characteristics of the patients in the study are provided in Table I. There were fifty-nine unimalleolar, twenty-eight bimalleolar, and thirteen trimalleolar ankle fractures with the displacement of the osseous fragments ranging between 0 and 20 mm. One patient in each group had a bimalleolar ankle fracture with total dislocation of the talus. One patient who had been treated with a cast had an associated deltoid ligament injury, whereas five patients who had been treated with a brace had such an injury. The most common cause of the fractures in both groups was an injury that occurred while walking. Four patients treated with a cast and two treated with a brace had minor preoperative skin abrasions.

A total of twelve patients were lost to follow-up before the two-year follow-up examination. The cast group and the brace group consisted of fifty patients each at two and six weeks; fifty and forty-nine patients, respectively, at twelve weeks; forty-seven and forty-nine at fifty-two weeks; and forty-two and forty-six at the two-year follow-up examination. Four patients were unwilling to continue in the study, three had moved to another area, two were lost to follow-up because of alcohol-related problems, and one each had a severe knee ligament injury, a herniated lumbosacral disc with complicated peripheral neurological symptoms, and complicated rheumatoid arthritis.

Clinical Assessment

Swelling of the ankle, atrophy of the calf muscles, and active range of motion of the ankle joint at the six, twelve, and fifty-two-week and two-year follow-up examinations are shown in Table II. No significant differences between the groups were found when these parameters were compared. With regard to joint laxity, no patient in either group had chronic medial instability of the ankle at the two-year follow-up examination. In the group treated with a cast, one patient had moderate and one patient had severe chronic lateral instability of the ankle as demonstrated by the anterior drawer test. In the group

treated with a brace, three patients had moderate and one patient had severe chronic lateral ankle instability.

Complications

There were no perioperative complications. In the group treated with a cast, eight patients had a postoperative complication. Four of them had a superficial wound infection that was treated with oral antibiotic therapy, two had deep-vein thrombosis of the immobilized leg that was diagnosed with both venography and ultrasound, one had chronic skin irritation, and one had chronic dysesthesia of the skin. The two patients with deep-vein thrombosis were treated uneventfully with subcutaneous injections of miniheparin followed by oral administration of warfarin for three months. In the group treated with a brace, thirty-three patients had a postoperative complication. Sixteen of them had a superficial wound infection that was treated with oral antibiotic therapy; four, a deep wound infection that was treated with intravenous antibiotic therapy; three, dehiscence of the wound; three, chronic dysesthesias; two, chronic skin irritation; and one each, local skin necrosis, chronic allodynia, loss of internal fixation, refracture of the lateral malleolus sixteen months after the primary fracture as a result of a new inversion injury of the ankle, and a postspinal headache. The difference in the overall complication rates between the group treated with a cast (16%) and the group treated with a brace (66%) was significant ($p = 0.0005$). Preoperatively, four patients treated with a cast and two treated with a brace had a skin abrasion. Of these patients, one in each group had a postoperative wound infection (a superficial infection developed in a patient managed with a cast, and a deep infection developed in a patient managed with a brace). There was no documented postoperative arthritis or osteomyelitis in either group. The average hospital stay (and standard deviation) was 3 ± 1 days (median, three; range, two to six days) in the group treated with a cast and 3 ± 1 days (median, three; range, two to ten days) in the group treated with a brace. All

TABLE II Data on the Ankles*

	Group Treated with a Cast	Group Treated with a Brace
Six-week examination		
No. of ankles	50	50
Swelling of the ankle *(mm)*	20 ± 19	18 ± 14
Atrophy of the calf muscles *(mm)*	–10 ± 24	–4 ± 12
Range of motion *(deg)*		
Plantar flexion	37 ± 20 (–22 ± 13)	40 ± 10 (–20 ± 13)
Dorsiflexion	5 ± 4 (–7 ± 6)	15 ± 5 (–7 ± 5)
Twelve-week examination		
No. of ankles	50	49
Swelling of the ankle *(mm)*	22 ± 12	18 ± 14
Atrophy of the calf muscles *(mm)*	–8 ± 10	–6 ± 10
Range of motion *(deg)*		
Plantar flexion	61 ± 26 (–12 ± 8)	54 ± 10 (–13 ± 9)
Dorsiflexion	11 ± 5 (–5 ± 5)	11 ± 5 (–5 ± 5)
Fifty-two-week examination		
No. of ankles	47	49
Swelling of the ankle *(mm)*	11 ± 9	10 ± 8
Atrophy of the calf muscles *(mm)*	–2 ± 7	0 ± 18
Range of motion *(deg)*		
Plantar flexion	63 ± 11 (–6 ± 7)	65 ± 7 (–5 ± 7)
Dorsiflexion	13 ± 5 (–2 ± 4)	13 ± 6 (–2 ± 4)
Two-year examination		
No. of ankles	42	46
Swelling of the ankle *(mm)*	9 ± 9	6 ± 11
Atrophy of the calf muscles *(mm)*	0 ± 7	1 ± 8
Range of motion *(deg)*		
Plantar flexion	71 ± 22 (–4 ± 6)	65 ± 8 (–2 ± 8)
Dorsiflexion	14 ± 5 (–1 ± 4)	14 ± 5 (–2 ± 4)

*The values are given as the mean and the standard deviation, with the difference in range of motion between the injured and the uninjured ankle in parentheses.

TABLE III Comparison of the Groups with Respect to the Functional Ankle Scores*

	Group Treated with a Cast	Group Treated with a Brace
Six-week examination		
No. of ankles	50	50
Olerud and Molander ankle score *(points)*	54 ± 13 (55; 25-85)	52 ± 14 (50; 10-75)
Kaikkonen et al. ankle score *(points)*	–	–
Twelve-week examination		
No. of ankles	50	49
Olerud and Molander ankle score *(points)*	75 ± 14 (80; 40-100)	75 ± 13 (75; 40-100)
Kaikkonen et al. ankle score *(points)*	59 ± 10 (60; 30-80)	57 ± 12 (60; 30-75)
Fifty-two-week examination		
No. of ankles	47	49
Olerud and Molander ankle score *(points)*	89 ± 8 (90; 50-100)	88 ± 9 (90; 45-100)
Kaikkonen et al. ankle score *(points)*	82 ± 13 (85; 40-100)	82 ± 13 (85; 45-100)
Two-year examination		
No. of ankles	42	46
Olerud and Molander ankle score *(points)*	87 ± 8 (90; 55-100)	87 ± 9 (90; 50-100)
Kaikkonen et al. ankle score *(points)*	85 ± 9 (85; 60-100)	83 ± 10 (85; 55-100)

*The scores are given as the mean and the standard deviation, with the median and the range in parentheses.

fractures in both groups united clinically by six weeks and radiographically by twelve weeks. There was no radiographically documented postoperative loss of reduction of the ankle fracture in either group, although one patient in the group treated with a brace had loss of internal fixation without displacement of the ankle fracture at the two-week follow-up examination. The fixation hardware was removed seven weeks after the primary operation. The patient continued to recover uneventfully without any additional complications.

Functional Assessment

Functional recovery, according to the scoring systems of Kaikkonen et al.[35] and Olerud and Molander[34], is presented in detail in Table III. With the numbers available, no significant differences between the two groups could be detected with respect to functional outcome at any of the follow-up evaluations.

Return to Work

For patients who were employed, the mean duration (and standard deviation) between the operation and return to work was 63 ± 13 days (median, sixty-three days; range, thirty-three to ninety-eight days) for the cast group and 65 ± 19 days (median, sixty-two days; range, eight to 131 days) for the brace group; the difference was not significant.

Discussion

In this prospective randomized study of the long-term outcome for patients who were treated with a cast compared with those who were treated with a functional ankle brace in the first six weeks following internal fixation of Weber type-A and type-B ankle fractures, we did not find a significant difference between the two postoperative treatment methods. At the two-year follow-up evaluation, all ankles had healed well clinically, the radiographic (anatomic) result was comparable in the two groups, and the patients' ability to return to work was virtually identical. Previously, van Laarhoven et al.[28] found only a temporary benefit in the subjective evaluation, but not in the overall clinical result, in patients who were managed with mobilization in a below-the-knee walking cast compared with those who were managed with non-weight-bearing with crutches after internal fixation of an ankle fracture. Egol et al.[22] found that patients who were treated with a functional brace with early movement had higher functional outcome scores (with use of the ankle-grading system of Mazur et al.[36]) at six and twelve weeks, six months, and one year after internal fixation of an ankle fracture than did patients who were treated with a below-the-knee cast, although the difference was significant ($p = 0.0276$) only at six weeks. In the present study, we used two different well-validated ankle-grading systems to assess the functional recovery of the injured ankle[34,35]. The functional scores in the two study groups were very similar at the two-year follow-up examination, with a good or excellent score, according to the system of Olerud and Molander[34] and that of Kaikkonen et al.[35], achieved, on both measures, by 93% of the patients managed with a cast and by 91% and 96%, respectively, of those managed with a brace.

The theoretical basis for the use of functional treatment in orthopaedic practice is the fact that early weight-bearing and the avoidance of complete immobilization have been shown to facilitate the restoration of the range of motion of the injured joint, to decrease the development of soft-tissue atrophy, and to prevent the development of osteoporosis[15,30]. Early functional treatment with a removable ankle brace has been used successfully in the treatment of injured lateral liga-

ments of the ankle[29,31,32,37-44]. The proposed benefits of functional bracing and early exercises after operative treatment of an ankle fracture have been the potential saving in costs, the better long-term functional outcome, and the absence of complications[22]. In our study, functional treatment with an ankle brace led to fewer (none compared with two) episodes of deep venous thrombosis and slightly less soft-tissue swelling and atrophy of the calf muscles during the early phases of recovery (the first twelve postoperative weeks), but it was associated with an intolerably high rate of postoperative wound complications (wound dehiscence, infection, and delayed healing of the wound). Recently, Hoiness and Stromsoe[45] reported that wound closure problems, blistering, wound-edge necrosis, and infection following open reduction and internal fixation of an ankle fracture can be attributed to delayed surgery. As we did not find any correlation between the presence of preoperative skin abrasions or the timing of surgery and postoperative wound complications, we suspect that the increased prevalence of wound-healing problems in our study was attributable to the use of the functional ankle brace. According to the manufacturer, the brace used in the present study, through its design of preinflated air cells, provides effective pneumatic pulsating circumferential compression on the ankle during walking to "milk away" edema. Although such a feature can naturally be considered beneficial in an ankle injury with intact skin (an ankle ligament sprain), it probably would have been more appropriate to use a cast for the first two weeks after open reduction and internal fixation in the brace treatment group to decrease the number of postoperative wound problems. In fact, Ahl et al., in two studies comparing patients with an ankle fracture who were managed with early and late weight-bearing in a walking cast[12,17], showed that early weight-bearing in a below-the-knee walking cast is a safe postoperative treatment modality, but it is associated with an increased risk of superficial wound infection. Thus, they recommended that weight-bearing should begin only after primary wound-healing has occurred. In this context, it should also be noted that, both in our study and that of Hoiness et al.[46], the minor soft-tissue complications associated with the treatment of ankle fractures had no influence on the long-term functional outcome of the ankle.

With regard to the potential cost-savings, the overall costs that are attributable to the treatment of any injury can be divided into direct and indirect costs, with the direct costs consisting of those related to the initial treatment of the injury in the hospital and the indirect costs involving those related to the lost productivity of the individual. The ratio of indirect-to-direct costs varies depending on such factors as the severity of the injury, the patients' employment, the complication rate associated with the treatment options, and the social structure of a given society. As there were no major complications (except for the two patients who had deep-vein thrombosis, which was resolved successfully with proper medication) in either group and the average hospital stay and the time to return to work were virtually identical in both groups, one can assume that neither treatment option proved to be superior from an economic standpoint. However, a definite conclusion with regard to the apparent fact that there was no difference between the two groups could only be made if our study had a proper (power calculation-derived) sample size. As we did not perform such an analysis prior to initiating the study, a flaw that is common to virtually all orthopaedic clinical trials[47], caution is warranted in interpreting our data in this regard.

In conclusion, the results of this study show that the postoperative treatment of ankle fractures can be accomplished equally effectively both with use of a plaster cast and with a functional brace. The long-term results of these two postoperative treatments are comparable with respect to the subjective, objective, clinical, radiographic, and functional outcome. Although some beneficial effects of early functional treatment can be observed, the high prevalence of postoperative wound complications warrants caution in the early use of a functional brace in the immediate postoperative care after internal fixation of an ankle fracture. ■

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